

## **REMARKS**

### ***Status of the Claims***

Claims 26-29 are pending; claims 1-25 are canceled; and claim 27 is amended.

Claim 27 has been amended to recite visible particles. Applicants assert that this element is not new as the phrase "without any particles that are visible" was added with claim 26 in the December 11, 2007 amendment and subsequently removed with the March 12, 2008 Amendment. Thus Applicants assert that this amendment does not raise a new issue, and is an attempt to put the claims in position for allowance.

No new matter has been added.

### **1. Claim Rejections under 35 U.S.C. § 112, Written Description**

The Examiner rejects claims 26-29 as lacking written description in the Specification as filed. The Examiner states that the limitation "wherein the emulsion is dispersed without any particles that have a diameter of 100µm or more. . ." does not have support in the Specification as filed. The Examiner asserts that such a limitation is "new matter." The Examiner also asserts that the Specification does not disclose a Bacillus Calmette-Guerin cell wall skeleton encapsulated in an oil wherein the emulsion is dispersed without any particles that have a diameter of 100 µm or more, and therefore one of skill in the art would not consider the Applicant to be in possession of the claimed genus of oil in water emulsions. Applicants respectfully traverse.

Applicants submit that the Specification amply supports a limitation "wherein the emulsion is dispersed without any particles that have a diameter of 100µm or more. . .". While the Examiner's citations to the Specification are accurate, Applicants submit that the Examiner has not included the Figures in her analysis. According to Federal Circuit precedent, support for written description can be found in the words, structures, figures, diagrams, formulas, etc. of the Specification. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). Furthermore, the exact terms need not be used *in haec verba. Id.* In particular, figures 10-14, discussed on page 24, lines 3-18, describe the agglutination reaction and the show that the

particles of the invention are significantly less than 100µm in size.

Furthermore, the Specification discloses that a preparation that is “appropriately dispersed” is one “wherein the crude particles are not visible.” (Specification page 18, lines 15-17). The Specification discloses that “the crude particles that are visible have usually a diameter of about 100 µm or more.” (Specification page 18, lines 17-18). Therefore, to obtain an “appropriate” dispersion of the invention, the particles of the invention are not visible. Consequently, “the emulsion” of the invention “is dispersed without any visible particles that have a diameter of 100µm or more.” (Claim 27). Thus, the Specification amply indicates to one of skill in the art that Applicants had possession of the claimed invention at the time of filing because it discloses what an “appropriate dispersion” is, describes in detail the size of the particles, and gives working examples of an appropriate dispersion according to claim 27.

## **2. Claim Rejections under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects claim 27 as indefinite. The Examiner states that “wherein the emulsion is dispersed without any particles that have a diameter of 100µm or more. . .” is indefinite because “it does not recite an upper limit.” The standard for determining whether a claim is definite is “If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2.” *Exxon Research and Engineering Co. v. United States*, 60 USPQ 1272, 1276 (Fed. Cir. 2001).

In *Exxon*, the court analyzed two elements which are pertinent here. First, the court determined that the term “substantial absence of slug flow” was not indefinite because one of skill would understand that the reason for requiring a lack of “substantial slug flow” was disclosed in the Specification. (*Id.* at 1280). Second the court determined that the term “particles of average diameter,  $d_p > 5\mu\text{m}$ ” was not indefinite because, though the term “does not set forth any upper limit on particle size,” no limitation on maximum size was required for the claim to be definite. (*Id.* at 1282) (“A patent claim to a fishing pole would not be invalid on indefiniteness grounds if it contained a limitation requiring that the pole be ‘at least three feet long,’ even though a 50-foot-long fishing pole would not be very practical.” *Id.* at 1282).

Applicants respectfully submit that one of skill would understand from the Specification that the emulsion of the claimed invention lacks visible particles that have a diameter of 100µm or more. Like *Exxon*, the present invention discloses a reason for not having large particles, namely, that the mixture does not aggregate and therefore is not stable. (Specification, page 15, lines 9-18). Also like *Exxon*, Applicants are not required to provide an upper limit. Moreover, the Specification establishes that an appropriate particle size is one where the particles are not visible, and that an appropriate particle is one where the cell walls are encapsulated in oil, and where the formulation is stable after lyophilization of the oil-in-water emulsion. (Specification, page 11, lines 14-16). Thus one of skill would understand from the Specification that the solution does not have any visible particles that have a diameter of 100µm or more. Applicants submit that the claim is clear and respectfully request that the rejection be withdrawn.

The Examiner also states that it is unclear whether the term "particle" refers to the cell wall skeleton or the oil particles within the oil-in-water emulsion. Applicants submit that the disclosure in the Specification at page 4, lines 3-8, supporting that "the bacterial component is encapsulated in an oil droplet," and discussing "the *particle diameter* distribution of the *oil droplets*" sufficiently clarifies the relationship between the oil droplets and the cell wall skeleton. Applicants respectfully request that the rejection be withdrawn.

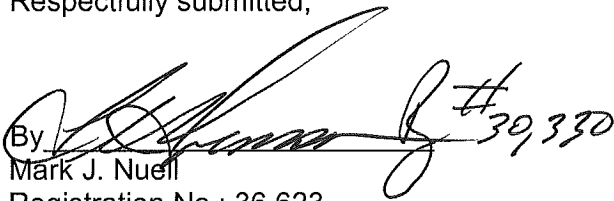
#### 4. Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Registration No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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